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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,452	09/11/2003	Lutz Biedermann	58779/B884	4918

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/660,452

Applicant(s)

BIEDERMANN ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 8, 14-16, 19 and 20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 7, 8, 14-16, 19, and 20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Applicant's reply of October 30, 2006, does not identify which of the claims are readable on the elected species, as required in the Office action mailed on February 8, 2006 (page 2, lines 10-12), and fails to particularly point out the support in the original disclosure for each of the newly added claims and revisions to previously filed claims (MPEP §§ 714.02 and 2163.06). New claims 21-27 are apparently based in part on the description of alternative embodiments in paragraph 0046 of the original specification. The newly claimed embodiment and the previously elected species, however, possess mutually exclusive features, and the respective rotational axes would seem to be located at different portions of the spine. (The election requirement of February 8, 2006, was based on the assumption that current and future claims comply with 37 CFR 1.83(a).) Therefore, claims 21-27 are withdrawn as being drawn to a non-elected species.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7, 8, 14-16, 19, and 20 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter involving the vertebral column and hence the human body itself (MPEP § 2105, last paragraph). It is recommended that in claim 7, second to last line, "extends" be replaced by something like --is oriented to extend-- or --is configured to extend-- in order to avoid positively reciting the actual implanted state in which the prosthesis is attached to the vertebral column.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 8, line 2, "their outer edges" lacks a proper antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Navas, US 5,540,688. Figures 3, 5, and 10 illustrate base and top plates **3** and a biconvex core (Figure 10) comprising an upper body **110a** and **70**, a lower body **110b** and **70**, and an intermediate elastic body **130** (column 5, lines 47-49; column 4, lines 62-64) separating the upper and lower bodies and extending primarily in a plane generally perpendicular to the vertebral column. Sliding engagement among the components is described at column 3, lines 62-65, and column 4, lines 13-20, for example. Regarding claim 14, the elongated, central portion of element **110** can be viewed as a mandrel because it provides structural support (column 4, lines 55-60) to the implanted system, including the spine, and thus helps prevent relative movement between the plates **3** about a longitudinal or central axis generally parallel to the spine. Regarding claim 15, elements **70** define a bore within which is provided a connecting

sleeve **120** capable of at least indirectly engaging the plates **3** (via dumbbell element **110**).

Instant claims 19 and 20 do not positively recite the “cylindrical casing”, which instead appears in functional language pertaining to the cylindrical nature of the base plate; nevertheless, Figure 1 shows the cylindrical form of the plates **3** along with cylindrical casings **2c** each having at least two teeth defined along the lateral notches **2f** and capable of engaging an adjacent wall of a vertebral body (Figure 5).

Claims 8, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navas, US 5,540,688. Regarding claim 8, in the variant of Figure 5, to replace or supplement the implants **2** with well known vertebral plates having engagement teeth would have been obvious to the ordinary practitioner in order to better secure the device to the spine and to lessen stress concentrations imposed on the respective vertebral bodies. Regarding claims 15 and 16, the dumbbell element **110** taking the form of a threadably engaged screw and sleeve would have been obvious in order to provide better control over the pre-tensioning of the element **110** and pre-compressing of body **120** (column 5, lines 18-20).

The Applicant’s remarks have been considered but are deemed moot in view of the new grounds of rejection, which were necessitated by the extensive modifications to the scope of claim 7. Therefore:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse
Primary Examiner
Art Unit 3738